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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,106	02/25/2004	Ming-Hui Wei	CL001180DIV	1623

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EXAMINER	
KIM, ALEXANDER D	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,106	WEI ET AL.	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 1-23 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 20-21, drawn to an isolated peptide related to a lanosterol synthase homologue of SEQ ID No: 2, classified in class 435, subclass 193.

II. Claim 3, drawn to an isolated antibody that binds to a related lanosterol synthase homologue of SEQ ID No: 2, classified in class 530, subclass 387.1.

III. Claims 4-6, 8-9 and 22-23, drawn to nucleic acids encoding related polypeptide of SEQ ID No: 2, classified in class 536, subclass 23.2.

IV. Claim 7, drawn to a transgenic non-human animal, classified in class 800, subclass 13.

V. Claim 10-11, drawn to a method for producing peptides related to SEQ ID No: 2 by a host cell, classified in class 435, subclass 70.1.

VI. Claim 12, drawn to a method of detecting polypeptide related to lanosterol synthase of SEQ ID No: 2, classified in class 435, subclass 4.

VII. Claim 13, drawn to a method of detecting nucleic acids which encode related polypeptide of SEQ ID No: 2, classified in class 435, subclass 6.

VIII. Claims 14-16 and 19, drawn to a method of identifying a modulator of peptides related to SEQ ID No: 2 or expression of the peptide, classified in class 435, subclass 4.

IX. Claim 17, drawn to a pharmaceutical composition and pharmaceutically acceptable carrier, classified in class 424, subclass 439.

X. Claim 18, drawn to a method of treating disease or condition mediated by a human enzyme protein, classified in class 514, subclass 1.

3. The inventions are distinct, each from the other because of the following reasons:

Group I-IV, IX are related to each other by the virtue of all products in Groups are related to a lanosterol synthase and its homologues. For example, a protein of Group I is encoded by nucleic acid of Group III. A protein of Group I is used to make an antibody of Group II. A transgenic non-human animal of Group IV is made from the gene of Group III, which encodes a protein of Group I. A pharmaceutical composition of Group IX is found by assaying a protein of Group I. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group I-IV, IX are distinct inventions because they are structurally, functionally and chemically distinct

products. While both polypeptides of Group I and antibodies of Group II are structurally related by virtue of their contiguous sequence of amino acids, they are distinct structures based on their three-dimensional structures wherein proteins fold into a variety of structures and antibodies maintain a specific, Y-shape. Polypeptides are functionally distinct from antibodies because antibodies merely recognize a cognate peptide whereas polypeptides catalyze a specific chemical reaction with a substrate. A nucleic acid of Group III is consists of nucleotides, which is chemically distinct from all other groups and has a unique function of encoding a protein. A transgenic non-human animal of Group IV is distinct from any other Groups because it is a whole living organism. A pharmaceutical composition of Group IX is made up of many chemical molecules, which binds to the protein and correct abnormal physiology.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. For example, the polypeptide of Group I can be made by organic synthesis.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I-II, IV and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the peptide of Group I can be used in a size exclusion chromatography for peptide size determination, the antibody of Group II can be used in a protease assay, the transgenic non-human animal of Group IV can be used to prepare a genomic nucleic acid.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different

classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group VII are related because the gene encoding protein of Group I is detected by the method of Group VII. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group I and Group VII are mutually exclusive and not obvious variants because Group I is a peptide made up of many amino acids whereas the Group VII is a method of detecting nucleic acids. The method step of Group VII neither use nor make the product of Group I thus they are not capable of using together. The Group I and Group VII have different function because the protein of group I catalyze a specific reaction and the method of Group VII can be used to detect nucleic acid. By the reasons above, Group I and Group VII do not overlap.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using

different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I-IV, IX and Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the peptide of Group I can be used in a size exclusion chromatography for peptide size determination, the antibody of Group II can be used in protease assay, the nucleic acids of Group III can be used as template for polymerase chain reaction for gene amplification, the transgenic non-human animal of Group IV can be used to make genomic DNA, the pharmaceutical composition of Group IX can be used to manufacture a drug.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I, III and Group X are related because the method of treatment by Group X is related to the disease associated with the protein of Group I encoded by the nucleic acid of Group III. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the Group I, III are mutually exclusive and not obvious variants because steps involved in the method of Group X neither use nor make products of Group I, III. Group I, III and X have different mode of function because the protein of Group I is used to catalyze a specific reaction, the nucleic acid of Group III is used for encoding a protein of Group I and the method of Group X is used to alleviate the abnormal symptoms by the protein of Group I. Therefore, Group I, III and X do not overlap in scope.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II and Group V, VII are related product and processes by the virtue of Group II can bind to the protein produced a method of Group V and the gene encoding

the protein can be detected by a method of Group VII. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the isolated antibody is mutually exclusive and not obvious variant because processes of Group V and VII neither use nor make the antibody of Group II in method steps. The Group II and Group V, VII have different mode of function because the antibody of Group I has function of binding to a protein whereas the method of Group V, VII have function of making a protein and detecting a nucleic acid, respectively. Thus Group II and Group V, VII do not overlap in scope.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II, IV, IX and Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the antibody of Group II can be used in a protease assay. The transgenic non-human animal of Group IV can be used to make a genomic nucleic acid. The pharmaceutical composition can be used in enzyme inhibition assay.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the nucleic acid of Group III can be used as a template for polymerase chain reaction.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different

classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III and Group VI are related because the nucleic acid of Group III encodes protein, which is detected by the method of Group VI. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the Group III and VI are mutually exclusive and not obvious variants because Group III is a product consist of nucleic acids and Group VI is method of detecting a polypeptide, which is chemically and functionally distinct product. Additionally, method steps of Group VI neither make nor use the product of Group III thus they are not capable of using together. Group III and Group VI have different function because the nucleic acid of Group III is used to encode a protein whereas the methods of Group VI are used to find a specific nucleic acid.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using

different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III-IV and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the nucleic acids of Group III can be used as template for polymerase chain reaction for gene amplification; the transgenic non-human animal can be used to prepare a genomic DNA.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the transgenic non-human animal of Group IV can be used to prepare a genomic DNA.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group V-VII and Group IX are related because the product of Group IX can be used to treat a disease associated with a protein, which is made by methods of Group V and assayed by the method of Group VI. Also, the nucleic acid detected by the method of Group VII encodes a protein associated with disease, which can be treated by the product of Group IX. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group V-VII and Group IX are mutually exclusive and not obvious variants because Group V-VII are method processes involving a

making protein, detecting protein and detecting nucleic acid whereas the product of Group IX are for treating a disease or condition. Also, method steps of Group V-VII neither make nor use the product of Group IX. Group V-VII and Group IX have different function and mode of operation as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group V-VIII and X are related processes to each other because; the protein made by Group V methods can be assayed by a method of Group VI, the gene encoding the protein made by Group V methods can be detected by a method of Group VII, the method of Group VIII can identify a molecule which modulate a protein prepared by the method of Group V, the method of Group X treats disease associated with the protein prepared by the method of Group V. The related inventions are distinct from each other if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group V-VIII and X are mutually exclusive and not obvious variants to each other because the

methods steps involved in each Groups are distinct from each other. Group V involves protein purification steps. Group VI involves protein assay steps. Group VII involves running an agarose gel with ethidium bromide or a hybridization of nucleic acid steps. Group VIII involves steps using the host cell containing a lanosterol synthase gene and assay how much protein is made inside the host cell. Group X involves steps of providing an effective compound into a patient. Also, the end result from each method is distinct from each other. Each Group has different mode of function or effects because; the method of Group V makes the peptide, the method of Group VI detects the peptide, the method of Group VII detects the nucleic acid, the method of Group VIII identifies the modulator molecules and the methods of Group X treats the disease associated with the enzyme. Thus, Group V-VIII and X do not overlap in scope compared to each other.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim
Date

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER